SEP - 9 2003

510 (K) Summary

Device Classification Name	Lamp, Non-heating for Adjunctive use in pain therapy
Regulation Number	890.5500
510(k) Number	K030622
Device Name	The Axiom BioLaser LLT Series - 1
Applicant	Axiom Worldwide 9423 Corporate Lake Drive Tampa, Florida 33634
Contact	James J. Gibson
Product Code	NHN

The Axiom Bio Laser LLT Series – 1 is a single diode laser which produces an Output power of no more than 5 mW of energy with a 660 nm wavelength. The Axiom BioLaser LLT Series – 1 is substantially equivalent to the Erchonia PL2000 with an output power of no more than 5 mW and with a 635 nm wavelength. The wavelength although they differ, do not substantially effect the Transmission through the skin. The technical aspects of both devices are Significantly equivalent, therefore, achieving the same treatment For the intended use of providing temporary relief of minor chronic neck And shoulder pain of musculoskeletal origins.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 9 2003

Mr. James J. Gibson
President
Axiom Worldwide
9423 Corporate Lake Drive
Tampa, Florida 33634

Re: K030622
Trade/Device Name: Axiom BioLaser LLLT Series-1
Regulation Number: 21 CFR 890.5500
Regulation Name: Lamp, Non-heating for adjunctive use in pain therapy
Regulatory Class: II
Product Code: NHN
Dated: June 10, 2003
Received: June 11, 2003

Dear Mr. Gibson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K030622

Device Name: **Axiom BioLaser LLLT Series-1**

Indications For Use:

Intended Use

The Axiom BioLaser LLLT Series-1 is for adjunctive use in providing temporary relief of minor chronic Neck and shoulder pain of musculoskeletal origins.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030622